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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,762	DAILEY ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

APPLICANT'S INVENTION

1. The instant invention is directed to a method of delivering a therapeutic agent to a desired location in the by administering a formulation comprising magnetic particles and at least one therapeutic agent and using a magnetic field to move a portion of the magnetic particle formulation to the desired location.

Note: Claims 1-13 are pending.

DOUBLE PATENTING REJECTIONS

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1, 2, and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,135,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to using a magnetic fluid containing formulation, administering it to the eye, and using a magnetic field (i.e., applying a magnetized scleral buckle to the eye) to move the formulation to the desired location. The claims differ in that the instant invention specifically states that at least one therapeutic agent is present while the patented invention does not specifically state that such agent is present. However, a skilled practitioner in the art would recognize that a treatment process (see patented claim 1) involves a therapeutic agent. Hence, a therapeutic agent is inherent in the patented formulation.

4. Claims 1 and 11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/010,567. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims disclose a method wherein a magnetic formulation is utilized and its placement is controlled once administered to the subject. The claims differ in that the claims of the instant invention

specifically state that a magnetic field is used to move a portion of the magnetic formulation to the desired location and that at leas one therapeutic agent is present. The claims of 11/010,567 do not exclude the presence of a therapeutic agent. Furthermore, a skilled practitioner in the art would recognize that a method of medical repair of living tissue is simply a method of treating a subject in need of medical repair of living tissue. Thus, since a treatment process involves administering a therapeutic agent to a subject, it would be obvious to incorporate a therapeutic agent in the magnetic particle formulation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,749,844. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to administering a magnetic particle formulation to a subject and applying a magnetic field (i.e., magnetized scleral buckle) to move a portion of the magnetic particle formulation to a desired location. The claims differ in that the claims of the instant invention specifically state that a therapeutic agent is utilized. However, a skilled practitioner in the art would recognize that a method of treating retinal detachment in the eye involves administering a therapeutic agent since a treatment process involves the use of a therapeutic agent to treat the condition.

6. Claims 1 and 11-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5 of U.S. Patent No. 6,612,311. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to delivering a compound comprising magnetized particle formulation and transporting the formulation to the desired location. The claims differ in that those of the instant invention specifically state that a therapeutic agent is present. However, it would be obvious to one of ordinary skill in the art to incorporate a therapeutic agent because patented claim 5 discloses that the magnetized particle formulation may be a radiotherapeutic.

112 FIRST PARAGRAPH REJECTION

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the therapeutic agent, anti-VEGF (see Example 1, in specification), does not reasonably provide enablement for all therapeutic agents. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a method of delivering a therapeutic agent to a desired location as set forth in independent claim 1 wherein a magnetic particle formulation is administered to a subject and a magnetic field is used to move at least a portion of the magnetic particle formulation to the desired location within the eye.

(2) State of the prior art

The references of record do not indicate which specific therapeutic agents or class of therapeutic agents are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 1 encompasses a vast number of possible therapeutic agents.

(4) Level of predictability in the art

The art pertaining to the therapeutic agents is highly unpredictable. Determining the various types of therapeutic agents or class of therapeutic agents that are useful in nuclear spin tomography requires various experimental procedures and without guidance that is applicable to all therapeutic agents, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claim 1 encompasses a vast number of therapeutic agents. Applicant's limited guidance does not enable the public to prepare such a numerous amount of therapeutic agent combinations. There is no directional guidance for a therapeutic agent except at-VEGF as set forth in Example 1of the specification. Hence, there is no enablement for all possible permutations and combinations of the therapeutic agents.

(6) Existence of working examples

Independent claim 1 encompasses a vast number of therapeutic agent combinations. Applicant's limited working examples do not enable the public to prepare such a numerous amount of agents. While Applicant's claims encompass a plethora of possible therapeutic agents, the specification provides only for anti-VEGF as set forth in Example 1 of the specification.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible therapeutic agents known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-13: The claims as written are ambiguous because one cannot readily ascertain what therapeutic agents Applicant intends to be compatible with the instant invention (see independent claim 1). In addition, it is unclear what type of magnetic field Applicant is referring to that is used to move the magnetic particles (see independent claim 1). Please clarify in order that one may readily ascertain what is being claimed. It

should be noted that since one could not ascertain what is being claimed in independent claim 1, all claims depending thereon are also ambiguous.

103 REJECTION

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-3 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevenson et al (Journal of Magnetism and Magnetic Materials, 2001, 225(1-2), 47-58) in view of Dailey et al (Journal of Magnetism and Magnetic Materials, 1999, 194 (1-3), 140-148).

Stevenson et al disclose magnetic cobalt dispersions in poly(dimethylsiloxane) fluids that are used in the treatment of retinal detachments (see entire document, especially, abstract). Stevenson et al disclose various magnetic particle formulations such as the synthesis of a cobalt magnetic fluid stabilized with)5530 g/mole PDMS(– (5000 g/mol PCPMS) – (5530 g/mol PDMS) block copolymer in toluene (pages 49-50, section 2.4; see also the formulations on page 50, sections 2.5 and 2.6; page 55, Table 2). Stevenson et al fail to specifically state that a therapeutic agent is present in the magnetic particle formulation.

Dailey et al disclose the use of a magnetic fluid formulation for repairing retina detachment the formulation is administered to a subject and a magnetize encircling scleral buckle is used to move the formulation to the desired location. Dailey et al disclose that a formulation may be placed insider the vitreous cavity. In addition, it is disclosed that with the appropriate magnetic fluid inside the vitreous cavity, the encircling magnetized scleral buckle and magnetic fluid would produce a ring of silicone oil in apposition to the retinal periphery. As a result, the central vitreous cavity would be free of the magnetic fluid, and there would be no contact between the magnetic fluid and the lens, anterior chamber structures, or macula which would avoid the complications of currently available treatment modalities (see entire document, especially, abstract; pages 140-141, bridging paragraph; pages 141-142, bridging paragraph). Furthermore, it is disclosed that the magnetic formulation may comprise nickel particles (page 142, columns 1-2, bridging paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Stevenson et al using the teachings of Dailey et al and generate a method of delivering a therapeutic agent comprising a magnetic particle formulation and at least one therapeutic agent as set forth in independent claim 1 because (a) Stevenson et al disclose a magnetic cobalt formulation that is administered to a subject in the treatment of retinal detachments. (b) Stevenson et al disclose in its conclusions on page 58 (first complete paragraph) that a drop of the magnetic polymeric fluid would be introduced into the vitreous cavity and held at the site of a retinal hole by encircling magnetic scleral buckle. Thus, since the magnetic particle

formulations contain other ingredients, those ingredients may be considered to be therapeutic agents since there are no limitations placed on Applicant's therapeutic agent and the additional agents present in the formulations are used to obtain enhanced results. Dailey et al is cited for its additional teachings involving the repairing of the retina using a magnetic particle formulation in combination with a magnetized encircling scleral buckle. In particular, it is disclosed that the desired location may be the macula and that the particle sizes may range from 4-10 nanometer. Furthermore, since both documents are directed to administering a magnetic particle formulation and using a magnetic field to move a portion of the formulation to a desired location, the references may be considered to be within the same field of endeavor. Thus, their teachings are combinable.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1618

September 15, 2005